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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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EXAMINER

FRENEL, VANEL

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,366

Applicant(s)

HESS, CATHY ILYSE

Examiner

Vanel Frenel

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[Signature]

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>10/1/04</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice to Applicant

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/04 has been entered.

2. This communication is in response to the RCE filed on 7/15/04. Claims 1, 9, 13, 15 and 17 have been amended. Claims 18-19 have added. Claims 1-11, 13 and 15-19 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11, 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511), Hennessy et al (6,277,071), Gibson et al (6,077,082) and further in view of Closed dressings after laser skin resurfacing by

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(James P Newman, R James Koch, Richard L.Goode; Archives of Otolaryngology , Head & Neck Surgery; Jul 1998).

(A) As per claim 1, Dang and Hennessy disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67) to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56)

issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

Dang, Hennessy and Gibson do not collectively disclose "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and

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application of dressings to a wound"; monitoring and comparing said recorded clinical actions taken by said clinician, "at the time of performance of said clinical action".

However, these features are known in the art, as evidenced by James. In particular, James suggests "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3); monitoring and comparing said recorded clinical actions taken by said clinician, "at the time of performance of said clinical action" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of James within the collective teachings of Dang, Hennessy and Gibson with the motivation of providing patient characteristics of overall acceptance, comfort, and ease of maintenance were recorded with a visual analog scale (See James Page 1, Paragraph 9).

(B) As per claim 2, Hennessy discloses a method according wherein said gathering of said patient care data includes applying a risk assessment tool comprising a rating scale to objectively characterize the subjective condition of said patient's skin and wound (See Hennessy Fig.20; Col.10, lines 29-60).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Hennessy discloses a method according wherein said rating scale identifies factors most closely associated with the formation of a selected malady (Col.2, lines 36-67 to Col.3, line 8).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Hennessy discloses a method wherein said factors are associated with parameters that are identified and assessed by said clinician, and a rating number assigned to each of said parameters that corresponds to said clinician's objective assessment of a wound/skin condition (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Hennessy discloses a method wherein a finite numerical score is selected from a preselected range and assigned to each of said parameters (Col. 9, lines 29-63).

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The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Hennessy discloses a method wherein a numerical score at or above a preselected value is indicative of a high risk for development of said malady (Col.9, lines 64-67 to Col.10, line 23).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Hennessy discloses a method wherein said parameters, along with their assigned scores, are stored at a known, searchable, and retrievable location in said data storage means (Col.9, lines 29-63).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(H) As per claim 8, Hennessy discloses a method wherein said monitoring includes reviewing each of said parameters, and identifying a most likely course of intervention to be followed by said clinician (Col.11, lines 1-45).

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The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Dang discloses a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means of a general purpose computer as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as a data record in said data storage means (See Dang, Col.12, lines 27-67) to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56);

issuing an alert notice to said clinician of an identified variation from said identified clinical pathway at the time of performance of said clinical action identified as

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a variance so as to allow said clinician to alter said clinical action (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

Dang, Hennessy and Gibson do not collectively disclose "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound"; monitoring and comparing said recorded clinical actions taken by said clinician, "at the time of performance of said clinical action".

However, these features are known in the art, as evidenced by James. In particular, James suggests "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3); monitoring and comparing said recorded clinical actions taken by said clinician, "at the time of performance of said clinical action" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of James within the collective teachings of Dang, Hennessy and Gibson with the motivation of providing patient characteristics of overall acceptance, comfort, and ease of maintenance were recorded with a visual analog scale (See James Page 1, Paragraph 9).

(J) As per claim 10, Hennessy discloses a method wherein said gathering of said patient care data includes observing and recording a patient's vital signs (Col.7, lines 26-51).

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The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 9, and incorporated herein.

(K) As per claim 11, Hennessy discloses a method wherein said recorded vital signs are each compared to a preselected value for said vital sign and monitored for deviations that are indicative of a high risk for development of a skin malady (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 9, and incorporated herein.

(L) As per claim 12, Hennessy discloses a method wherein said implementing said identified clinical pathway and recording clinical actions taken by said clinician includes implementing a skin and wound care regimen (Col.2, lines 1-35; Col.6, lines 30-67).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 9, and incorporated herein.

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(M) As per claim 13, James discloses a method wherein said skin and wound care regimen are monitored for deviations that are indicative of a high risk for deterioration of said skin and wound (See James Page 3, Paragraphs 1-6).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are and as discussed above in the rejection of claim 9, and incorporated herein.

(N) As per claim 14, Hennessy discloses a method wherein said regimen comprises selection and application of dressings to a wound (See Hennessy Fig.20; Col.6, lines 30- 67).

The motivation for combining the respective teachings of Dang, Hennessy, Gibson and James are as discussed above in the rejection of claim 9, and incorporated herein.

(O) Claim 15 differs from claims 1 and 9 by reciting a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data according to a predetermined regimen for diagnosing a malady of the skin; (B) storing said patient care data in a data storage means of a general purpose computer.

As per this limitation, it is noted that Dang discloses (C) identifying an appropriate clinical pathway from a plurality of pathways for treating said diagnosed malady (See Dang Col.12, lines 27-67 to Col.13, line 27); monitoring said clinical actions taken by

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said clinician to determine variations from said identified clinical pathway (See Hennessy, Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56); issuing an alert notice to said clinician of an identified variation from said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43) and James discloses "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3); (E) monitoring and comparing said recorded clinical actions taken by said clinician "at the time of performance of said clinical action" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3).

Thus, it is readily apparent that these prior art systems utilize a predetermined regimen to perform their specified function.

The remainder of claim 15 is rejected for the same reason given above for claims 1 and 9, and incorporated herein.

(P) As per claim 16, Hennessy discloses a method wherein said regimen comprises answering a questionnaire that quantifies a patient's satisfaction with his/her health status (See Hennessy Col.2, lines 8-35).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 15, and incorporated herein.

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(Q) As per claim 17, Dang discloses disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67); monitoring and comparing said recorded clinical actions taken by said clinician, while said clinician is treating said patient, to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56); issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

Dang, Hennessy and Gibson do not explicitly disclose "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound"; (E) monitoring and comparing said recorded

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clinical actions taken by said clinician, "at the time of performance of said clinical action", to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway.

However, these features are known in the art, as evidenced by James. In particular, James suggests "wherein said clinical action includes implemented a skin and wound care regimen comprising selection and application of dressings to a wound" (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3); (E) monitoring and comparing said recorded clinical actions taken by said clinician, "at the time of performance of said clinical action", to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See James, Page 3, Paragraphs 2-6; Page 5, Paragraphs 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of James within the collective teachings of Dang, Hennessy and Gibson with the motivation of providing patient characteristics of overall acceptance, comfort, and ease of maintenance were recorded with a visual analog scale (See James Page 1, Paragraph 9).

(R) Claim 18 recites the same limitations as claim 1 above, and is therefore rejected under the same rationale, and incorporated herein.

(S) Claim 19 recites the same limitations as claim 1 above, and is therefore rejected under the same rationale, and incorporated herein.

Response to Arguments

5. Applicant's arguments filed on 07/15/04 regarding claims 1, 9, 15, and 17 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 07/15/04.

(A) At pages 11-14 of the 07/15/04 response, Applicant's argue that the features in the 07/15/04 amendment are not teach, suggest or disclose by the applied references. In response, all of the limitations which Applicant disputes as missing in the applied references, in the 07/15/04 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Dang, Hennessy, Gibson and James based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action, and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

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Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches wound dressing package (5,749,842), method and kit for wound evaluation (6,193,658), comprehensive treatment of the aging face— cutaneous and structural rejuvenation by David A Sherris, Clark C Otley, George B Bartley. Mayo Clinic Proceedings. Rochester; Feb 1998).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on Monday-Thursday on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

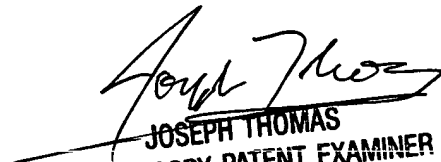
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October 17, 2004


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SUPERVISORY PATENT EXAMINER
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